

REMARKS

Claims 29-38 remain in this case, claim 37 having been restricted out pursuant to a prior restriction requirement.

Claims 28-30, 32, 34-36 have been rejected as obvious over Razavi U.S. Patent No. 5,676,685 in view of Kropf U.S. Patent No. 4,760,849. Claim 31 was rejected as obvious over Razavi U.S. Patent No. 5,676,685 in view of Kropf U.S. Patent No. 4,760,849 and Khosravi U.S. Patent No. 5,824,054. Claim 33 was rejected as obvious over Razavi U.S. Patent No. 5,676,685 in view of Kropf U.S. Patent No. 4,760,849 and Herzog PCT Publication No. WO 98/08482. Claim 38 was rejected as obvious over Razavi U.S. Patent No. 5,676,685 in view of Kropf U.S. Patent No. 4,760,849 and Ragheb U.S. Patent No. 5,873,904.

The Cited Art

Razavi U.S. Patent No. 5,676,685 discloses a removable, temporary stent 10 comprising a wire coil 12 enclosed within a biodegradable/bioabsorbable coating 14. Coating 14 includes outer and inner layers 16, 18. Outer layer 16 may include various agents (column 3, lines 22-30). Inner layer 18 surrounds a wire coil 12 and is made of a material that can be softened or liquefied when heated to permit wire coil 12 to be pulled out from coating 14 leaving coating 14 in place. "Removal of core wire 12 will of course be accomplished at such time as the stent has served its temporary purpose." Column 2, lines 34-36.

Kropf U.S. Patent No. 4,760,849 discloses a ladder-type planar blank which can be made into a coil spring useful as a filter for thromboses. The coil spring has apertures to facilitate ingrowth of tissue into the spring material. See column 1, lines 61-63 and column 2, lines 51-55. This reference only discloses a stent. It teaches away from adding a graft material because a stated intention of the invention is to permit tissue ingrowth through the apertures. There is no recognition that the addition of a graft material would be useful or possible.

Khosravi U.S. Patent No. 5,824,054 shows a graft stent 10 made of a coiled sheet 11 of lattice or mesh to which a biocompatible graft material 12 is affixed. Graft material may have a desired permeability and may be impregnated with one or more drugs to effect a desired treatment. (Column 4, lines 61-66.) Graft stent 10 is wrapped on to itself like a roll of tape. Figures 5A-5C show placement

of graft stent 10 into a body lumen 100 to treat an aneurysm 101. The graft stent 10 is expanded by a balloon 47 and is locked into its enlarged diameter configuration by teeth 15 engaging openings 16. (See figure 1 and column 5, lines 32-40.) The device is stated to be useful to "stem blood loss through an arterio-venous fistula, or provide a positive seal at the ends of a graft to reduce bypass flow." (Column 2, lines 31-35; column 3, lines 3-8.)

Herzog PCT Publication No. WO 98/08482 discloses several embodiments:

The surface of, for example, a stent, catheter, etc. is coated with a polymeric coating containing sodium nitroprusside. The coating permits the NO to diffuse into the blood or body tissue. See page 6, last paragraph. The coating can be formed by immersing the stent, catheter, etc. into a solution or colloidal suspension including the polymer and sodium nitroprusside. See page 13, first full paragraph.

Figure 2, page 15 discloses a stent and grooves on the inner wall. Sodium nitroprusside can be deposited in the grooves and covered by a polymer coating.

Page 19, example 6 of Herzog discloses a metal stent with grooves along its length. A nitroprusside powder is placed in the grooves and the stent is coated with the PVC solution. The number of coatings, and thus the thickness of the PVC, can be changed to obtain the desired flux of NO.

Ragheb U.S. Patent No. 5,873,904 discloses a medical device 10 including a structure 12, typically a vascular stent 12, composed of an elastic/non-elastic, biodegradable/non-biodegradable base material 14, such as stainless steel, nitinol, polymers, etc. Stent 12 is shown to have several layers of materials coated thereon. At least one layer 18 of a bioactive material is on the surface of stent 12. An outer porous layer 20 is on layer 18 to provide controlled release of the bioactive material. A porous/non-porous layer 16 may be used between the bioactive layer 18 and stent 12. A second bioactive layer 22 may be used between porous layer 20 and bioactive layer 18; if so, an inner porous layer 24 may be used between the bioactive layers 18, 22.

The Cited Art Distinguished

Independent claim 28 has been amended to emphasize that the porous tubular graft material extends along the single coiled path defined by the stent body and completely surrounds and covers the entire coiled stent body.

Claim 28 would not have been obvious over Razavi in view of Kropf because it would not have been obvious to combine them to arrive at the invention of claim 28. The basic concept of Razavi is to permit the removal core wire 12 after temporary stent 10 has served its purpose. Therefore, it would have been contrary to the teachings of Razavi to substitute the ladder-type planar blank of Kropf for wire coil 12 of Razavi because after coating the ladder-type planar blank of Kropf with the coating 14 of Razavi, it would not be possible to remove the ladder-type planar blank by softening or liquefying the inner layer 18 of coating 14 because of the numerous side elements and connector elements. In addition, Kropf only discloses a stent. Kropf teaches away from adding a graft material because a stated intention of the Kropf invention is to permit tissue ingrowth through the apertures. There is no recognition that the addition of a graft material would be useful or possible.

Even if it were assumed that it would have been obvious to replace the wire coil 12 of Razavi with the ladder-type structure of Kropf (which, as discussed above, would not have been the case), the resulting structure would not be that of claim 28. That is, the resulting structure would not include a porous tubular graft material that (1) extends along a single coiled path defined by the stent body, and (2) completely covers and surrounds the entire coiled stent body to create a coiled stent graft. Rather, the resulting structure would include segments of coating 14 extending along three different coiled paths and numerous lateral paths. In addition, it would not have been obvious to modify this resulting structure by replacing the coating 14 of Razavi with the presently claimed porous tubular graft material that extends along the single coiled path defined by the stent body to completely cover and surround the entire coiled stent body, not just elements of the stent body, because there was no recognition of the desirability to do so.

Accordingly, independent claim 28 is allowable over the cited art.

The **dependant claims** are directed to specific novel subfeatures of the invention and are allowable for that reason as well as by depending from novel parent claims.

CONCLUSION

In light of the above remarks and the amendments to the claims, applicants submit that the application is in condition for allowance and action to that end is urged. If the Examiner believes a

telephone conference would aid the prosecution of this case in any way, please call the undersigned at (650) 712-0340.

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